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EXAMINER

MONBLEAU, DAVIENNE N

ART UNIT PAPER NUMBER

2878

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,171

Applicant(s)

HJERTMAN ET AL.

Examiner

Davienne Monbleau

Art Unit

2878

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-84, 86-106 and 108-110 is/are pending in the application.
- 4a) Of the above claim(s) 85-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-84 and 108-110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Claims 102-106 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 10.

Claims 86-101 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Applicant's election with traverse of invention I (Claims 40-84 and 108-110) in Paper No. 10 is acknowledged. The traversal is on the ground(s) that it would not be unduly burdensome for the Examiner to examine Invention II (Claims 86-101) as well because both inventions are classified in class 604. This is not found persuasive because invention I is classified in class 604/404 while invention II is classified in class 604/189. Since these inventions are classified in two separate subclasses, this is sufficient to meet the restriction requirements set forth in MPEP 808.02 (A).

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claims 75 and 76 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim *cannot depend from any other multiple dependent claim*. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Regarding Claim 48, Examiner suggests inserting -- of movement -- after "the speed" to have consistent claim language with Claim 47.

Priority

This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a division of Application No. 08/886,398, filed 07/01/1997." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50 and 77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481

(Bd. App. 1949). In the present instance, claim 50 recites the broad recitation "in the non-visible range", and the claim also recites "preferably in the infrared range" which is the narrower statement of the range/limitation.

Regarding Claim 77, the phrase "being a functional property as defined" is indefinite because there is no indication what it is defined by.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 77-80 and 84, to the extent taught and understood, are rejected under 35 U.S.C. 102(e) as being anticipated by Walker et al. (US 5,651,775). Regarding Claim 77, Walker et al. disclose in Figure 1 a method for operating a preparation delivery device comprising a container (50) with an opening, a mechanism operable to deliver at least part of the preparation in the container through the opening (30), attachment means (40), and a sensor system arranged to detect at least one predetermined functional property, wherein said sensor system comprises transmitting radiation towards the container position (140) and receiving at least part of the affected radiation (99). Walker et al. further teach in Figure 10 detecting a functional property (plunger position) via detectors (280). This encompasses comparing the characteristics of the received radiation with a predetermined characteristic representative for the

predetermined property to establish whether or not the predetermined property of the container is present.

Regarding Claims 78 and 79, Walker et al. disclose in Figure 15 (500) reproducing details from the container position in at least two dimensions providing a representation in the form of pixels in the at least two dimensions.

Regarding Claim 79, Walker et al. disclose in column 16 lines using a CCD to image the plunger position. (Note that a standard 1014 CCD is a two-dimensional pixel array).

Regarding Claim 80, Walker et al. disclose in Figure 10 and in Figure 16 rotating/sweeping the mirror to produce an image of the plunger position.

Regarding Claim 84, Walker et al. disclose in Figure 10 that said functional property is plunger position (282).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 40-42, 44, 45, 49-57, 64, 65, 67-71, 73-76, 81-83, 108 and 109, to the extent taught and understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (US 5,651,775) in view of Goldman (US 5,750,998).

Regarding Claim 40, Walker et al. teach in Figure 1 a method for operating a preparation delivery device comprising a container (50) with an opening, a mechanism operable to deliver at least part of the preparation in the container through the opening (30), attachment means (40), and a sensor system, wherein said sensor system comprises transmitting radiation towards the container position (140) and receiving at least part of the affected radiation (99) in a non-imaging way. Walker et al. do not teach detecting a predetermined property of the container or its content, but rather reading markings. Goldman teaches in Figure 1 an apparatus for detecting a predetermined property within a container (14) comprising transmitting radiation (46), receiving at least part of the affected radiation (66), and comparing the characteristics of the received radiation with a predetermined characteristic representative for the predetermined property to establish whether or not the predetermined property of the container is present (spectroscopic analysis). (See Goldman column 6 lines 43-67). Both Walker et al. and Goldman teach improving the safety of drug administration. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the predetermined characteristic sensing means in Walker et al., as taught by Goldman, to provide accurate qualitative and quantitative measurements of components of a liquid medium within a bag/container, thus increasing the safety of drug delivery means to patients. (See Goldman column 3 lines 39-49).

Regarding Claim 41, Goldman teaches in Figures 4-7 that the radiation is affected by transmission.

Regarding Claims 42, 82, and 108, Goldman teaches in column 3 lines 35-38 that said container is translucent or transparent and in Figure 1 that at least some radiation is transmitted into the container (14).

Regarding Claims 44, 45, and 109, Walker et al. teach in Figures 6A-D initiation steps on the container (such as applying a label).

Regarding Claim 49, Goldman teaches in Figure 1 that said container (14) is kept stationary relative to said sensor during radiation reception.

Regarding Claim 50, Goldman teaches in column 5 lines 35-38 that said radiation transmitted might be IR.

Regarding Claims 51-53 and 81, lacking any criticality, it would have been obvious to one of ordinary skill in the art at the time of the invention to use various beam altering techniques, such as de-focusing, diverging, and broad-space angling, since it is well known in the art to use result effective variables as a matter of obvious design choice.

Regarding Claim 54, Goldman teaches in column 5 lines 35-38 that various radiation source may be used. Therefore, it would have been obvious to one of ordinary skill in the art to use a broadband source because more wavelengths would be covered and thus more properties of the container or the liquid within could be determined.

Regarding Claims 55 and 83, it would have been obvious to one of ordinary skill in the art to determine the optimum respective positions of the transmitter and receiver to either detect

the reflective properties of or within the container or the transmissive properties. Either method will be able to establish whether a predetermined property exists.

Regarding Claim 56, Goldman teaches in Figure 1 maintaining transmitter (46) and receiver (66) at a distance from the container.

Regarding Claim 57, lacking any criticality, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a receiver that covers a specific area since it has been held that using a result effective variable is a matter of obvious design choice.

Regarding Claim 64, Walker et al. teach in Figure 10 detecting a functional property of the container (50).

Regarding Claim 65, Walker et al. teach in Figure 10 that said functional property is plunger position (282).

Regarding Claim 67, the purpose of a detector is to receive radiation and analyze it accordingly. Thus, it is obvious that it will use the total radiation it detects in its analysis in order to efficiently compare data and accurately determine whether the property exists.

Regarding Claim 68, Goldman teaches in Figure 1 a static response.

Regarding Claims 69 and 70, Walker et al. teach in Figure 16 and in column 18 lines 43-67 that the establishment of a property presence is based on a dynamic change from the receiver and recording that dynamic change.

Regarding Claim 71, Walker et al. teach in Figure 11D that more than one property presence is established (label and plunger position).

Regarding Claim 73, Walker et al. do not teach modulating the transmitted radiation. However, it would have been obvious to one of ordinary skill in the art at the time of the

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invention to modulate the transmitted radiation, for example amplifying the signal, to have a stronger signal for more accurate data comparison and property presence determination.

Regarding Claim 74, Walker et al. teach in Figure 1 that said radiation is transmitted and received with stable orientation in relation to stationary parts of the mechanism.

Claims 43, 46-48, and 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (US 5,651,775) in view of Goldman (US 5,750,998), as applied to Claim 40 above, and in further view of Manique et al. (US 5,523,560).

Regarding Claim 43, Walker et al. do not teach moving the container in relation to stationary parts of the mechanism. Manique et al. teach in Figure 7A a method for inspecting liquid-filled containers comprising rotating a container (10) to create a two-dimensional image of its contents. It would have been obvious to one of ordinary skill in the art at the time of the invention to move the container in relation to stationary parts of the mechanism in Walker et al., as taught by Manique et al., as it is a suitable means to detect one or more test parameters of the liquid, the container, or both, simultaneously at a very high throughput having a high probability of rejecting defective containers and a low probability of rejecting non-defective containers.

Regarding Claims 46 and 110, see discussion on Claim 43.

Regarding Claims 47 and 48, Manique et al. teach throughout the specification various rotation rates in terms of RPMs. It would have been obvious to one of ordinary skill in the art at the time of the invention to use a particular rate to provide the most thorough scanning results with the best resolution.

Claims 58-63, 66, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (US 5,651,775) in view of Goldman (US 5,750,998), as applied to Claim 40 above, and in further view of Carman et al. (US 4,924,088).

Regarding Claim 58, Walker et al. do not teach providing a marking on the container. Carman et al. teach in Figure 1 providing markings (50) on an object. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide markings in Walker et al., as taught by Carman et al., to provide an inexpensive, cost efficient, information reader that is capable of detecting and evaluated individual markers. (See Carman et al. column 2 lines 3-8). Applicable to Walker et al, these markers could indicate additional properties of the container or the material therein.

Regarding Claim 59, Carman et al. teach in Figure 1 that markers with more than two discrete levels (51-53).

Regarding Claim 60, lacking any critically, it would have been obvious to one of ordinary skill in the art at the time of the invention to apply markers in more than one area since it has been held that using result effective variables is a matter of obvious design choice. Furthermore, adding additional markers in different areas is duplication of parts and requires the same technique as only having markers in one area.

Regarding Claims 61 and 62, Carman et al. teach in Figure 1 reading the markings statically.

Regarding Claim 63, Carman et al. teach in Figure 1 providing markings (51-53) with different absorptions (since they are different colors).

Regarding Claim 66, see discussion on Claim 61.

Regarding Claim 72, it would have been obvious to one of ordinary skill in the art at the time of the invention to detect/sense a marking property, as taught by Carman et al., along with a functional property, as taught by Walker et al., to have a multifunctional device that is capable of detecting/sensing properties of the container, the material within the container, and other properties that need to be encoded (i.e. vial number).

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Davienne Monbleau whose telephone number is 703-306-5803. (Note: as of January 20, 2004, the examiner's telephone number will be 571-272-1945). The examiner can normally be reached on Mon-Fri 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Porta can be reached on 703-308-4852. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0956.

Davienne Monbleau
DNM


ALBERT GAGLIARDI
PRIMARY EXAMINER